510(k) Summary – ResTraxx Online

K083814

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Date Prepared	5th Dec, 2008
Official Contact	Dr Lionel King V.P., Quality Assurance & Regulatory Affairs ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153 Australia Tel: +61 (2) 8884 1000 Fax: +61 (2) 8884 2021
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Noncontinuous ventilator (IPPB).
Proprietary Name	ResTraxx Online
Predicate Device(s)	ResTraxx System (K070746)
Reason for submission	Change to Indications for Use

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate device.

- Similar intended use
- Same operating principle
- Same technologies
- Same manufacturing process

Design and Verification activities were performed on ResTraxx Online as a result of the risk analysis and product requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate device (K070746). The new device complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)
- FDA Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (January 14, 2005)

Intended Use

ResTraxx Online is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been wirelessly transmitted from the patient's flow generator located in the home to the care giver. ResTraxx Online also provides remote settings capabilities.

It is intended to be used in the home only and with compatible S7 Elite, AutoSet Spirit, AutoSet Respond, S8 Series CPAP Systems, VPAP III, VPAP III ST, VPAP Malibu, VPAP Auto, VPAP Auto 25, VPAP S and VPAP ST variants positive airway pressure flow generators.

Device Description

General

The performance and functional characteristics of ResTraxx Online includes all the user features of the predicate device, ResTraxx System (K070746).

ResTraxx Online is designed to function with ResMed OSA treatment systems for the transfer, storage, retrieval and display of stored information from the flow generator to the clinician's PC, including remote settings functionality, via wireless transmission and web-based applications. Access to the data is limited to subscribers of the system. Patients cannot access the system.

ResTraxx Online comprises two distinct components, the wireless transmitter/receiver located on the flow generator and the Server System. Data taken from the flow generator is transmitted via a wireless network, stored in the ResTraxx Online database, transmitted via the Internet and displayed on the Clinical reviewer's PC.

Wireless Module

Wireless modules are designed to attach to a compatible ResMed flow generator using a docking mechanism. This mechanism allows the device to be electrically connected via the existing expansion port located at the rear of the flow generator. When attached, the wireless modules can automatically collect patient and machine information stored within the flow generator's memory. The wireless modules send information utilizing existing wireless networks providing coverage to large portions of the US population.

Server System

The Server System consists of several functional software modules that are designed to retrieve information from ResMed flow generators through the wireless network, store the information in a database and provide a secure interface into the system. The system allows users to schedule information retrieval and view patient and treatment information, including the ability to retrieve existing settings from and apply new settings to the flow generator remotely from the Clinical reviewer's PC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ResMed Limited
C/o Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064

Re: K083816
Trade/Device Name: ResTraxx Online
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 5, 2008
Received: December 22, 2008

Dear Mr. D'Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: ResTraxx Online

Indication for Use

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Prescription Use ___X___ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083816